

November 15, 2001

Office of Special Nutritionals, (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, D.C. 20204

Re: Statement of Nutritional Support Notification

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343 (r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of it's notification within 30 days of first marketing its product with the statements presented below:

Supplement Brand Name: CardioBALANCE Heart Support Formula

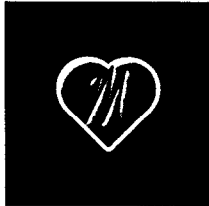
Supplement Ingredients: See attached brochure.

Text of Statements of Nutritional Support:

1. Nourishment for optimal cardiovascular health.
2. Helps maintain homocysteine levels that are already in the normal range.
3. Helps support already normal cardiovascular function.
4. Helps maintain normal blood flow to the already healthy heart and brain.
5. Helps support normal heart action and circulation that are already within normal limits.
6. Provides nutrients for increased tolerance during physical exertion.
7. Contains nutrients used by the heart that may help maintain normal blood pressure that is already within normal limits.
8. Contains nutrients used to support smooth muscle relaxation in already healthy blood vessels, which can help maintain blood pressure that is already within normal limits.

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9. Contains nutrients necessary for the management of potassium levels in heart tissues that are already in normal limits.
10. Helps maintain cholesterol levels that are already in normal range.
11. Contains nutrients that may help maintain total serum LDL cholesterol and HDL cholesterol ratios that are already in normal range.
12. Beneficial in helping to maintain the rate of oxidation of LDL cholesterol, which is already in the normal range.
13. Logo (normal heart with M for Mannatech).



14. Supports support elasticity in muscles, tendons and ligaments.
15. Helps support the body's ability to relax and dilate healthy arteries within normal limits.
16. Helps support the already normal flow of blood and oxygen to the heart.
17. Supports the already normal heart's ability to circulate blood.
18. Helps maintain blood pressure that is already in normal limits.
19. Helps strengthen the walls of already normal blood vessels.
20. Helps maintain already normal blood flow throughout the body.
21. Contains L-arginine to help support the production of nitric oxide.
22. Nitric oxide supports normal endothelial function, which supports the body's already healthy defense system.
23. Provides nutrients used by the body to support the natural relaxation of already healthy artery muscles.
24. Helps maintain dilation of already healthy blood vessels.
25. Helps maintain cholesterol and triglyceride levels that are already within normal limits.
26. Nutritional support to help maintain homocysteine levels that are already in the normal range.



27. Supports circulation throughout your 60,000 miles of already healthy blood vessels.
28. Helps support already healthy artery walls and heart muscle.
29. Provides nutrients used to support heart rhythms that are already within normal limits.
30. Nutritionally supports the body's natural defense mechanisms for an already healthy heart.
31. Nourishment for every beat of your heart.
32. CardioBALANCE™ - the heart formula for optimal cardiovascular support.
33. CardioBALANCE™ - for every beat of your heart.
34. Support for the maintenance of heart health.
35. Support healthy cardiovascular function.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Yours truly,

Dennis R. Sparkman, Ph.D.  
Director Global Regulatory Affairs

Enclosure: CardioBALANCE™ product label.

